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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,262	01/14/2004	Venkateswarlu Karicheti	MPI03-007P1RNOMNIM	6482

7590 03/28/2005
Millennium Pharmaceuticals, Inc.
40 Landsdowne Street
Cambridge, MA 02139

EXAMINER

DESAI, ANAND U

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,262	KARICHETI ET AL	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-7, drawn to a method for identifying a compound capable of treating a urological disorder, in the reply filed on December 20, 2004 is acknowledged. Claims 8-22 were cancelled. New claims 23 and 24 were added. Claims 1-7, 23, and 24 are currently pending and under examination.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, not all of the provisional applications upon which priority is claimed provide adequate support under 35 U.S.C. 112 for claims 1-7, 23, and 24 of this application. Upon review of the provisional applications it appears U.S.S.N 60/491,156, filed July 30, 2003 provides adequate support under 35 U.S.C. 112 for claims 1-7, 23, and 24 of this application. Particular support for claims disclosing the use of the sequences identified as SEQ ID NOs: 103 & 104 was found on pages 43-47 of U.S. provisional application 60/491,156. The priority date is July 30, 2003.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on December 20, 2004 is being considered by the examiner.

Specification

4. The disclosure is objected to because of the following informalities:
5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Methods and compositions for treating urological disorders using carboxypeptidase Z.

6. A preliminary examination of this application reveals that it includes terminology, which is so different from that which is generally accepted in the art to which this invention pertains that a proper search of the prior art cannot be accurately made. For example: the description of a urological cell is said to include brain and spinal cord cells (See page 5, paragraph 12).

Applicant is required to provide a clarification of these matters or correlation with art-accepted terminology so that a proper comparison with the prior art can be made. Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed).

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Objections

8. Claims 1, and 2 are objected to because of the following informalities:
9. In claim 1, suggest using the same phrase for the “candidate compound” throughout the claim. It appears as though the “compound”, and “test compound” in steps (a) and (b) are referring to the “candidate compound.”
10. In claim 2, the Markush group standard language would have an “and” prior to the last member, but there is an “or”. Suggest changing the “or” to “and.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
12. Claims 3-6, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
13. In claims 3, and 4 it is not clear if the polypeptide is referring to the amino acid sequence identified as SEQ ID NO: 104 or the candidate compound?
14. In claim 5, what does a urological cell mean? See also comment in objection of Specification. Does a urological cell include a neuron, and an astrocyte?
15. In claim 6, what does it mean to be “associated” with urinary incontinence or benign prostatic hyperplasia?
16. In claim 23, what is the “activity” of the polypeptide?

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

18. Claims 1-4, 7, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Song and Fricker (Journal of Biological Chemistry, Vol. 272, No. 16, pages 10543-10550 (1997)).

Song and Fricker disclose the cloning and expression of Human Carboxypeptidase Z (CPZ), a novel metallocarboxypeptidase. Song and Fricker tested CPZ activity in Sf9 cells with a variety of compounds that inhibit other members of the metallocarboxypeptidase gene family. The CPZ activity was inhibited by the chelating agent 1,10-phenanthroline (Table IV). The active site-directed inhibitors 2-mercaptoethyl-3-guanidinoethyl-thiopropionic acid (MGTA) and guanidinoethylmercaptosuccinic acid (GEMSA) inhibit CPZ activity at 1mM concentrations (Table IV, see also last paragraph of Results section). Therefore, Song and Fricker disclose a method of combining a candidate compound with CPZ and identifying if the candidate compound inhibits CPZ activity (current application, claims 1-4, 7, 23, and 24).

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19. Claims 1-7, 23, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Mack et al. U.S. Publication 2004/0076955 A1 (Effective filing date=July 3, 2001).

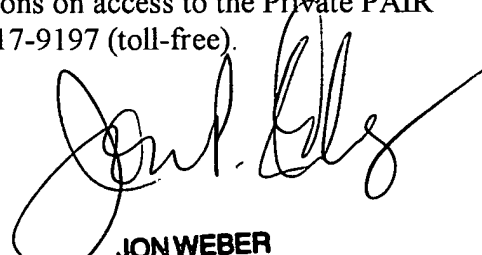
Mack et al. disclose the use of nucleic acid, polypeptides, and antibodies thereto that are involved in bladder cancer. The invention also relates to methods for identifying and using agents and/or targets that inhibit bladder cancer (see page 1, paragraph 2). The present invention provides a method for identifying a compound that modulates bladder cancer-associated polypeptide, the method comprising the steps of: (i) contacting the compound with a bladder cancer-associated polypeptide, the polypeptide encoded by a polynucleotide that selectively hybridizes to a sequence at least 80% identical to a sequence as shown in Tables 1A-13; and (ii) determining the functional effect of the compound upon the polypeptide. In one embodiment, the functional effect is an enzymatic effect, and the functional effect is determined by measuring ligand binding to the polypeptide (see page 2, paragraphs 31-34, and claim 19). Table 8A discloses carboxypeptidase Z as a gene predictive of bladder cancer progression (see page 122, 14th line down, current application, claim 1-7, 23, and 24).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 573-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 21, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER